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Dated: October 8, 2008

Signature: /Mark D. Russett/
Mark D. Russett, Reg. No. 41,281

Docket No.: 60004 (72021)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Uri Herzberg et al.

Confirmation No.: 7145

Application No.: 10/718,034

Art Unit: 1617

Filed: November 19, 2003

Examiner: D.R. Claytor

For: COMBINATION THERAPY FOR THE
TREATMENT OF PAIN

**REMARKS/ARGUMENTS IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants are in receipt of the final Office Action dated April 8, 2008 (the "Office Action"), and now request review of the Office Action. A request for an extension of time and a Notice of Appeal are filed herewith. The following remarks support Applicants' "Pre-Appeal Brief Request for Review" filed herewith. These remarks do not exceed five pages, do not present amendments, and are being filed with a Notice of Appeal, thereby satisfying the requirements for review.

Interview Summary

Applicants thank Examiners Claytor and Padmanabhan for the courtesy of a telephonic interview, conducted on July 1, 2008, with the undersigned representative. Also present was Seth Fidel, Ph.D., for the Applicants. The rejections under U.S.C. §102(e) and §103(a) were discussed, but no final agreement was reached.

The Office Action

In the Office Action, claims 43-45 and 48-50 stand rejected under 35 U.S.C. §102(e), as allegedly anticipated by Kyle et al., U.S. Patent No. 6,974,818 (the "Kyle patent"). This rejection is traversed.

First Clear Error and/or Omission in the Final Office Action:

(1) The Kyle Patent is not an effective reference for purposes of 35 USC 102(e)

Without agreeing that the disclosure of the Kyle patent would anticipate or render obvious any of the claims of the instant application if it were an effective reference, Applicants contend that the Kyle patent is not an effective reference against the claims presently under examination.

In the Interview of July 1, 2008 (summarized above), the Examiners indicated that they consider the Kyle patent (U.S. Patent No. 6,974,818) to form the basis for a rejection under 35 USC 102(e), and that the disclosure of the Kyle patent (rather than the disclosure of the Kyle priority application(s)) is relevant for the purposes of 35 USC 102(e). Applicants cannot agree. As discussed in the previous responses (filed August 10, 2007, and April 8, 2008), the disclosure of the Kyle patent is not available for citation under 35 USC 102(e) unless such disclosure also appears in one of the Kyle patent's priority provisional applications.

35 U.S.C. 102(e) provides, in relevant part, that:

“A person shall be entitled to a patent unless -

. . .

(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent”.

MPEP 706.02 (f)(1) I (B) states in part: “The 35 U.S.C. 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper benefit claims to prior U.S. applications under 35 U.S.C. 119(e) or 120 if the prior application(s) properly supports the subject matter used to make the rejection in compliance with 35 U.S.C. 112, first paragraph” (emphasis added). MPEP 2136.03(III) reiterates this requirement.

Therefore, an issued patent can be applied as a reference under 35 U.S.C. 102(e) only if the utility application, or one or more of the priority applications, was filed before the invention of the present claims by the present Applicants.

Applicants contend that the present claims are entitled to at least the filing date of the priority application USSN 60/433,363, filed December 13, 2002, to which the present application claims priority. The Kyle utility application (USSN 10/374,863) was filed on February 27, 2003, and thus was not filed "before the invention by the [present] applicant for patent".¹ Therefore, the disclosure of the Kyle utility application (USSN 10/374,863) and the Kyle patent as issued cannot be used in a rejection under 35 U.S.C. 102(e) unless such disclosure is present in an application to which the Kyle utility application properly claims priority.

It follows that the discussion in the Office Action of the disclosure of the Kyle patent (see, e.g., the Office Action at page 3, last paragraph) is irrelevant and improper as the basis for a rejection under 35 U.S.C. 102(e) unless that disclosure is found in one of the Kyle priority applications. The rejection of the present claims based on the asserted portions of the Kyle patent cannot stand.

Second Clear Error and/or Omission in the Final Office Action:

(2) The Kyle Priority application(s) do not anticipate the pending claims²

The present claims are directed to methods for inhibiting the development of tolerance to a narcotic analgesic in a patient (independent claim 43 and claims dependent therefrom) or methods for inhibiting the development of dependence on an opioid narcotic analgesic in a patient (independent claim 48 and claims dependent therefrom).

The MPEP states that, in order to anticipate a claimed invention, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." MPEP 2131 (emphasis supplied, citation omitted).

Furthermore, the Court of Appeals for the Federal Circuit has stated that "In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation . . . In other words,

¹ Solely for purposes of this discussion, the filing date of the priority application USSN 60/433,363 is mentioned as the latest date of invention of the present claims. Applicants reserve the right to assert an earlier date of invention.

² The Kyle utility application claims priority to two provisional applications. The Office Action does not allege that Kyle priority application 60/360,172 anticipates the present claims, and Applicants contend that it does not, so it will not be further discussed.

the prior art must enable the claimed invention.” Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., (Fed. Cir. 2008) (slip opinion published October 3, 2008, at page 3) (citations omitted).

The Office Action asserts that in the Kyle patent’s priority application 60/411,084, filed September 17, 2002, it is “taught that the compounds [of the Kyle priority application 60/411,084] treat addictive disorders.” Office Action at page 2. However, the disclosure in the ‘084 Kyle priority application regarding addictive disorders is limited to the lines (page 20, lines 15 and 20) previously cited by the Examiner (and similar language at page 21, lines 7-8 and 10-11), which merely recite that compounds disclosed therein “are useful for treating or preventing ... an addictive disorder.” Furthermore, there is no description at all in the Kyle ‘084 priority application of what an “addictive disorder” is.

As previously mentioned (see, e.g., the previous response filed April 8, 2008), the bare recitation of treating “an addictive disorder” in the Kyle priority application does not describe or enable methods for inhibiting the development of tolerance to or dependence on a narcotic analgesic, as recited in the pending claims under examination. Although the Office Action does not appear to address this point, Applicants contend that any contrary assertion in the Office Action is insupportable and cannot stand.

Notably, in Kyle’s 60/411,084 priority application, there is no disclosure at all (the ultimate in non-enablement) of most of the critical added citations from the Kyle patent 6,974,818 used in the Office Action in making the pending 35 U.S.C. 102(e) rejections (which are thus irrelevant under 35 U.S.C. 102(e), as discussed above).

Because the Kyle priority application does not describe or enable the subject matter of the present claims, the rejection under 35 U.S.C. 102(e) cannot stand and should be withdrawn. Reconsideration and withdrawal of the rejection is proper and the same is requested.

Rejection of claims under 35 U.S.C. §103(a)

In the Office Action (at pages 7-8), claims 46-47, 51-52, and 62-63 stand rejected under 35 U.S.C. §103(a), as allegedly unpatentable over Kyle et al., U.S.

Patent No. 6,974,818, in view of Bakthavatchalam et al., U.S. Patent No. 6,723,730 (the "Bakthavatchalam patent"). This rejection is traversed.

As noted above, the Kyle patent simply does not teach (for purposes of 35 U.S.C. 102(e)) what the Office Action asserts that it teaches. As also discussed above, the Kyle priority application(s) do not teach or suggest methods for inhibiting the development of tolerance to or dependence on a narcotic analgesic, as recited in the pending claims.

The Office Action does not contend that the Bakthavatchalam patent can supply these omitted teachings. Applicants contend the rejection over the Kyle patent in view of the Bakthavatchalam patent is therefore improper and should be withdrawn.

Reconsideration and withdrawal of the rejection is proper and the same is requested.

CONCLUSION

For at least the foregoing reasons, Applicants contend that the rejections of record should be withdrawn, and that the present application is in condition for allowance. Early and favorable consideration of the application is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 60004 (72021).

Dated: October 8, 2008

Respectfully submitted,

By /Mark D. Russett/
Mark D. Russett, Registration No.: 41,281
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 239-0100
Attorneys/Agents For Applicants